

WHAT IS CLAIMED IS:

1. A pharmaceutical formulation comprising a biologically active agent and methionine, wherein
5 said formulation demonstrates improved stability, and wherein said formulation does not contain human serum albumin.
2. A formulation according to Claim 1
10 wherein said methionine is present in a concentration of about 0.5mM-50mM.
3. A formulation according to Claim 2
15 wherein said active agent is selected from the group consisting of peptides, small molecules, carbohydrates, nucleic acids, lipids, proteins, and analogs thereof.
4. A formulation according to Claim 3
20 wherein said active ingredient is a protein.
5. A formulation according to Claim 4
wherein said protein is erythropoietin (EPO).
6. A formulation according to Claim 5
25 wherein said EPO has an amino acid sequence as depicted in SEQ ID NO:1.
7. A formulation according to Claim 6
30 further comprising a pH buffering agent which provides a pH range of about 5 to about 7.
8. A formulation according to Claim 7
further comprising a stabilizing amount of a sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl)

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derivative which is present in a concentration of about 0.001% to 0.1% (w/v).

5 9. A formulation according to Claim 4 wherein said protein is novel erythropoiesis stimulating protein (NESP) or a chemically modified form thereof.

10 10. A formulation according to Claim 9 wherein said NESP has an amino acid sequence as depicted in SEQ ID NO:2.

15 11. A formulation according to Claim 10 further comprising a pH buffering agent which provides a pH range of about 5 to about 7.

20 12. A formulation according to Claim 11 further comprising a stabilizing amount of a sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative which is present in a concentration of about 0.001% to 0.1% (w/v).

25 13. A pharmaceutical multi-dose formulation comprising a biologically active agent, a preservative, and methionine, wherein said formulation demonstrates improved stability, and wherein said formulation does not contain human serum albumin.

30 14. A formulation according to Claim 13 wherein said methionine is present in a concentration of about 0.5mM to 50mM.

15. A formulation according to Claim 14 wherein said active agent is selected from the group

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consisting of peptides, small molecules, carbohydrates, nucleic acids, lipids, proteins, and analogs thereof.

16. A formulation according to Claim 15
5 wherein said active ingredient is a protein.

17. A formulation according to Claim 16
wherein said protein is erythropoietin (EPO).

18. A formulation according to Claim 17
10 wherein said EPO has an amino acid sequence as depicted
in SEQ ID NO:1.

19. A formulation according to Claim 18
15 wherein said preservative is benzyl alcohol which is
present in a concentration of about 0% to 2% (w/v).

20. A formulation according to Claim 19
20 further comprising a pH buffering agent which provides
a pH range of about 5 to about 7.

21. A formulation according to Claim 20
further comprising a stabilizing amount of a sorbitan
mono-9-octadecenoate poly(oxy-1,2-ethanediyl)
25 derivative which is present in a concentration of about
0.001% to 0.1% (w/v).

22. A formulation according to Claim 16
wherein said protein is novel erythropoiesis
30 stimulating protein (NESP) or a chemically modified
form thereof.

23. A formulation according to Claim 22
wherein said NESP has an amino acid sequence as
35 depicted in SEQ ID NO:2.

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24. A formulation according to Claim 23 wherein said preservative is benzyl alcohol which is present in a concentration of about 0% to 2% (w/v).

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25. A formulation according to Claim 24 further comprising a pH buffering agent which provides a pH range of about 5 to about 7.

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26. A formulation according to Claim 25 further comprising a stabilizing amount of a sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative which is present in a concentration of about 0.001% to 0.1% (w/v).

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27. A method of stabilizing a pharmaceutical composition of a biologically active agent which comprises adding methionine to said composition in amount sufficient to inhibit oxidation of methionine residues in the amino acid sequence of said biologically active agents; wherein said formulation does not contain human serum albumin.

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